

II. Support for the Claims

Support for the amended claims can be found in the existing claims and throughout the specification as filed.

In claim 110, part (b), the nucleic acid sequence is defined as encoding a polypeptide that comprises a contiguous sequence of at least 16 amino acids from SEQ ID NO:4, at least 20 amino acids from SEQ ID NO:45 or SEQ ID NO:47 or at least 125 amino acids from SEQ ID NO:50. As a precaution, the word "about" has been removed prior to the term "16 amino acids from SEQ ID NO:4". The recitations of at least 20 contiguous amino acids from SEQ ID NO:45 or SEQ ID NO:47 and at least 125 contiguous sequence amino acids from SEQ ID NO:50 are supported by existing claims 115 and 125, respectively, and in the specification at least at page 16, line 27 through page 17, line 2 and at page 19, lines 9-10.

Claim 113 has been revised in accordance with claim 110, part (b).

Claims 114 and 115 have been canceled for simplicity

Dependent claim 116 has been revised so that the recited contiguous sequences refer only to SEQ ID NO:4, SEQ ID NO:45 and SEQ ID NO:47, and not to SEQ ID NO:50. The word "about" has been removed prior to the term "25 amino acids from", as a precaution

Claims 117 through 124 have been revised so that the recited contiguous sequences again refer only to SEQ ID NO:4, SEQ ID NO:45 and SEQ ID NO:47, and not to SEQ ID NO:50.

Claim 125 has been revised to remove the word "about" from the phrase "125 amino acids from SEQ ID NO:4, SEQ ID NO:45, SEQ ID NO:47 or SEQ ID NO:50", as a precaution regarding SEQ ID NO:50.

In claim 137, the P-TEFb large subunit protein is defined as binding to a P-TEFb kinase subunit protein to form a P-TEFb enzyme complex that promotes transcription elongation. This

is supported by current claim 49 and extensive sections of the specification, as summarized in the specification at page 18. The high stringency hybridization conditions are also defined as comprising hybridization in 50% formamide, 5× Denhardts' solution, 5× SSC, 25 mM sodium phosphate, 0.1% SDS and 100 µg/ml of denatured salmon sperm DNA at 42°C for 16 h followed by 1h sequential washes with 0.1× SSC, 0.1% SDS solution at 60°C, as supported by the specification at page 63, lines 21-25 and page 68, lines 23-27.

Claim 152 has been revised to use a combination of structural and functional language to define both the P-TEFb small subunit protein in part (a) and the P-TEFb large subunit protein in part (b). This language is again taken from claim 49, and is supported by extensive sections of the specification, as summarized at page 14 (small, kinase subunit) and at page 18 (large, cyclin subunit).

The same approach is used to clarify part (a) of claim 157, directed to the P-TEFb small subunit protein. In claim 157, part (b), Applicants have chosen a more functional recitation and have thus removed the reference to claim 113.

Claim 164 has been revised to reflect the contiguous sequence recitations of claim 113, which are provided as a supplement to the functional definition in claim 157, part (b).

Claims 165 and 166 have been canceled for simplicity

Claims 167 and 168 have been revised so that the recited contiguous sequences refer only to SEQ ID NO:4, SEQ ID NO:45 and SEQ ID NO:47, as described above for claims 119 and 124.

Claim 173 has been canceled for simplicity and claims 174 through 176 have been revised to depend on claim 168.

Dependent claim 177 has been revised to further limit claim 157, by changing the "at least 90%" definition of identity to "between 91% and about 95%" identity, as supported by claim 150.

Claim 181, part (a) has been amended to recite particular high stringency hybridization conditions, as described above for claim 137; and claim 181, part (b) has been amended to be more functional by removing reference to claim 113.

For brevity, claims 182 and 183 have been revised to refer to "said" high stringency hybridization conditions in claim 181, part (a).

Claim 185 has been revised in accordance with claim 113, as a supplement to the functional definition in claim 181, part (b).

Claim 190 has been revised to refer to particular high stringency hybridization conditions, as described above for claim 137.

Dependent claim 194 has been amended to further limit claim 181, by changing "at least 90%" to "between 91% and about 95%" identity, as supported by claim 150.

Each of claims 203 through 207 have been revised to replace the succinct phrase "in accordance with claim..." with the exact language of the referenced claims according to the present revisions.

Claims 209 and 210 have been canceled in preference to replacing the succinct phraseology.

It will therefore be understood that no new matter is included within the presently amended claims.

III. Decision on Petition, Finality and Response Period

The Decision on Petition mailed May 24, 2001 returned the application to non-Final status, so the present amendments are enterable as a matter of right. The claims would, in any event, be entitled to entry after a final rejection as they place the application in condition for allowance, essentially by adopting the Examiner's suggestions in a telephone interview.

The Decision on Petition also started a new period for response, to run three months from the May 24, 2001 mailing date of the Decision on Petition. The present document is therefore timely filed without extension fees.

IV. Interview Summary and Agreement on Patentability

Prior to submitting the present amendment, Applicant's representative, Shelley Fussey, telephoned Examiner Tung to discuss matters and a detailed telephone interview was held on August 22, 2001. Applicant appreciates Examiner Tung making himself available and the guidance provided, leading to tentative agreement.

Claim 149 was first discussed. Examiner Tung indicated that the "90% identity" structural definition in combination with the functional language ("wherein the P-TEFb large subunit protein binds to a P-TEFb kinase subunit protein to form a P-TEFb enzyme complex that promotes transcription elongation") placed this claim in condition for allowance.

Claim 137 was next discussed. It was agreed that as this claim is also directed to nucleic acid sequences that encode operative P-TEFb large subunit proteins, incorporating the functional language from claim 149 into this claim would be beneficial. It was then agreed that the claim could be placed in condition for allowance by either providing a nexus between the specification, knowledge in the art and the claim term "high stringency" or by incorporating defined high

stringency hybridization conditions into the claim. Applicant chooses the latter approach, thus placing this claim in condition for allowance.

Finally, claims 110 and 113 were discussed. Although agreement was not as definite as for claims 149 and 137, it was tentatively agreed that these claims could be placed in condition for allowance simply by revising the length of the contiguous amino acid sequences to overcome the novelty rejections of record. A review of the outstanding Office Action seems to indicate that a recitation of protein function is not necessary for allowance of these claims. Nonetheless, Applicant's representative indicated that these claims could later be revised by examiner's amendment if necessary.

Accordingly, agreement was reached that claim 149 was already allowable and that claim 137 would be allowable if revised as discussed. It was also tentatively agreed that claims 110 and 113 would be allowable if revised to distinguish over the Hillier sequences of record.

Applicant advised that a set of amended claims of the agreed scope and language would be submitted for entry in the case. It was also agreed that Examiner Tung would telephone Applicant's representative upon consideration of the present amendment, after which any non-allowable claims could be revised by examiner's amendment if necessary to secure allowance.

The present response thus implements the agreement reached and the application should be allowed on review, or at least, after a further telephone interview. The present actions are being taken without acquiescing with any of the outstanding rejections, but simply in order to progress the application to allowance as cost-effectively as possible, particularly in light of patent term issues.

V. Rejection of Claims Under 35 U.S.C. § 112, Second Paragraph

The outstanding Actions first rejected claims 137-148, 173-176, 181-183, 185-202, 208 and 211-216 under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite and for failing to particularly point out and distinctly claim the subject matter of the invention in regard to stringent hybridization. Claims 138-148, 174-176, 184-189, 191-202, 208 and 211-216 are also rejected as depending on the rejected base claims.

Applicant respectfully traverses for reasons of record. In any event, these concerns were addressed during the telephone interview and agreement was reached that the § 112, second paragraph rejection is overcome and will be withdrawn.

VI. First Rejection of Claims Under 35 U.S.C. § 112, First Paragraph

The outstanding Actions next rejected claims 137-148, 173, 181-184, 190 and 194-202 under 35 U.S.C. § 112, first paragraph, as allegedly not being supported by an enabling specification in connection with hybridization in general.

Applicant respectfully traverses and refers to the record to date. However, the stated concerns were addressed during the telephone interview and agreement was reached. As the present document implements the agreed strategy, this § 112, first paragraph rejection concerning hybridization is overcome.

VII. Second Rejection of Claims Under 35 U.S.C. § 112, First Paragraph

The outstanding Actions further rejected claims 149-151, 157-163, 177-184, 190, 194-202, 208 and 211-216 under 35 U.S.C. § 112, first paragraph, as allegedly not being supported by an enabling specification in connection with % identity.

Although Applicant respectfully traverses for reasons of record, these concerns were also addressed during the telephone interview and agreement was reached that the § 112, first paragraph rejection based on % identity is overcome and will be withdrawn.

VIII. Third Rejection of Claims Under 35 U.S.C. § 112, First Paragraph

The outstanding Actions next rejected claims 181-183 and 185-202 under 35 U.S.C. § 112, first paragraph, as allegedly not being supported by an enabling specification in connection with hybridization to SEQ ID NO:1 or SEQ ID NO:5.

In common with the earlier rejection, although Applicant respectfully traverses, the stated concerns were addressed during the telephone interview and agreement was reached. As the present document implements the agreed strategy, the § 112, first paragraph rejection concerning hybridization to SEQ ID NO:1 or SEQ ID NO:5 is also overcome.

IX. First New Rejection of Claims Under 35 U.S.C. § 102(b)

The outstanding Actions newly rejected claims 110, 113, 114 and 133-136 under 35 U.S.C. § 102(b) as allegedly being anticipated by Hillier. Hillier is said to disclose a polynucleotide that encodes a polypeptide comprising 18 amino acids of SEQ ID NO:45 and 18 amino acids of SEQ ID NO:47.

The relevant pending claims have been clarified to recite polynucleotides that encode contiguous amino acid sequences of at least 20 amino acids from SEQ ID NO:45 and SEQ ID NO:47. As a precaution, the term "about" has been removed from the closest length now recited in the claims. As agreed in the telephone interview, the first § 102(b) rejection is thus overcome.

X. Second New Rejection of Claims Under 35 U.S.C. § 102(b)

Finally, the outstanding Actions newly rejected claims 110, 113, 114-124 and 133-136 under 35 U.S.C. § 102(b) as allegedly being anticipated by Hillier, which is said to disclose a polynucleotide that encodes a polypeptide comprising 104 amino acids of SEQ ID NO:50.

The relevant pending claims have been clarified to recite polynucleotides that encode contiguous amino acid sequences of at least 125 amino acids from SEQ ID NO:50. Although not believed to be necessary, the term "about" has also been removed from the closest length now recited in the claims. As agreed in the telephone interview, the second § 102(b) rejection is thus also overcome.

XI. Objections to Claims

The outstanding Actions also objected to certain claims. These were not discussed specifically in the recent telephone interview, as Applicant believed that these matters could be readily addressed, as detailed below.

The outstanding Actions objected to claims 203-207, 209 and 210 under 37 C.F.R. § 1.75(c) as allegedly being in improper form in regard to multiple dependent claim format. Although Applicants respectfully traverse, the stated concerns have been addressed.

The Actions first assessed each of claims 203-207, 209 and 210 as being a "multiple dependent claim". In fact, each of these claims are singularly-dependent claims, which depend from only a single earlier claim. This is evident in that only one claim is recited in the preamble of these claims ("the recombinant host cell of claim 198, wherein...").

The objection also relies upon an interpretation of claim 198 as being a multiply dependent claim. In contrast, claim 198 is not a dependent claim, let alone a multiple dependent claim, but is an independent claim directed to a recombinant host cell. Although claim 198 does

"refer" to other claims, it is not "dependent upon" such claims. As claim 198 is directed to a different type of composition than claims 110, 113, 137, 149 and 152, *i.e.*, to a recombinant host cell rather than an isolated nucleic acid molecule, the status of claim 198 as an independent claim should be clear. The "reference" to other claims is simply a succinct form of definition for the various isolated nucleic acid molecules that may be comprised within the recited recombinant host cell.

Nonetheless, Applicant has elected to clarify each of claims 203, 204, 205, 206 and 207 by removing the succinct reference to nucleic acid molecules in accordance with claims 110, 113, 137, 149 or 152, respectively, and to insert the entire text of each of the foregoing claims into the recombinant host cell claims. For simplicity, Applicant elects to cancel claims 209 and 210 and instead rely on claim 208, which covers the same subject matter in independent form.

Accordingly, the objections are overcome and should be withdrawn.

The outstanding Actions further object to claim 137 as allegedly failing to further limit the subject matter of the claim from which it depends. The Action takes the position that claim 173 does not have a limitation that refers to a P-TEFb large subunit protein. Applicant believes that one of ordinary skill in the art would clearly understand the reference of claim 173 to such a large subunit protein, when read in the context of claims 157 and 137. However, in light of the clarifications that would be necessary to claim 173, both in terms of the present objection and the earlier rejection based upon stringent hybridization conditions, Applicant prefers to cancel 173 and rely on the remaining claims in the application, which cover this subject matter as a whole.

Accordingly, each of the objections have been overcome and should be withdrawn.

XII. Conclusion

This is a complete response to the outstanding Official Action. In conclusion, Applicant submits that, in light of the foregoing remarks and agreement in the telephone interview, the present case is in condition for allowance and such favorable action is respectfully requested. Should Examiner Tung have any questions or comments, or identify any remaining informalities, a telephone call to the undersigned Applicant's representative is earnestly solicited.

Respectfully submitted,



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